DEPARTMENT OF HEALTH AND HUMAN SERVICES

95115d

Food and Drug Administration
Seattle District
Pacific Region
22201 23rd Drive SE
Bothell, WA 98021-4421

Telephone: 425-486-8788
FAX: 425-483-4996

December 17, 2004

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

In reply refer to Warning Letter SEA 05-10

Roger Nutsch, Partner
U R Farms
363 N. 300 West
Jerome, Idaho 83338

WARNING LETTER

Dear Mr. Nutsch:

On July 22-23, 2004, our investigator inspected your dairy farm located at the 363 N. 300 West, Jerome, Idaho. That inspection confirmed that you offered a dairy cow for sale for slaughter as food that was adulterated under Sections 402(a)(2)(C)(ii) and 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act). You also caused the adulteration of an animal drug because the drug was used in a manner that does not conform to the approved use or the extralabel use regulations at Title 21, Code of Federal Regulations, Part 530 (21 CFR 530, copy enclosed). This caused the animal drug to be unsafe under Section 512(a) of the Act and adulterated within the meaning of Section 501(a)(5) of the Act.

On or about March 24, 2004, you sold a dairy cow identified with back tag number [redacted] and further identified as USDA-FSIS lab report # 433581, for slaughter as human food to [redacted]. U.S. Department of Agriculture (USDA) analysis of tissue samples collected from this cow identified the presence of penicillin at 0.20 parts per million (ppm) in the kidney. The established tolerance for residues of penicillin in uncooked edible tissues of cattle is 0.05 ppm, 21 CFR 556.510. The presence of penicillin above the established tolerance level in the edible tissues of these animals caused the food to be adulterated within the meaning of Section 402(a)(2)(C)(ii) of the Act.

A food is also adulterated under Section 402(a)(4) of the Act "if it has been prepared, packed, or held under insanitary conditions...whereby it may have been rendered injurious to health." As it applies in this case, "insanitary conditions" means that you hold animals which are ultimately offered for sale for slaughter as food under conditions that are so inadequate that medicated animals bearing potentially harmful drug residues are likely to enter the food supply. You lack an adequate system for assuring that animals to which you administer medication have been withheld from slaughter for appropriate periods of time to deplete potentially hazardous residues

of drugs. For example, our investigator noted that your treatment records are incomplete and that you lack an adequate inventory system for determining the quantities of drugs used to medicate your livestock.

The investigation also determined that you caused the adulteration of an animal drug within the meaning of Section 501(a)(5) of the Act when you failed to use the drug in conformance with its approved labeling or the extralabel use regulations at 21 CFR Part 530. Specifically, you used the drug Penicillin G Procaine in excess of the labeled dosage without the lawful order of a licensed veterinarian for such use and you failed to withhold the animal from slaughter for the appropriate withdrawal times. You administered 35 cc per day of Penicillin G Procaine to the cow, but according to the label, it should have been 14 cc per day.

Extralabel drug use is permitted only on the lawful order of a licensed veterinarian within the context of a valid veterinarian-client-patient relationship and in conformance with all other criteria set forth in 21 CFR Part 530, including that there may be no residue above established tolerance levels. Because your use of penicillin resulted in a residue above the established tolerance, your use of Penicillin G Procaine failed to comply with the extralabel use regulations. 21 CFR 530.11(d). In addition, because your extralabel use of penicillin was not on the lawful order of a licensed veterinarian, you also failed to comply with 21 CFR 530.10. You therefore caused the drug to be unsafe under Section 512(a) of the Act and thus adulterated within the meaning of Section 501(a)(5) of the Act.

It is not necessary for you to have personally shipped an adulterated animal in interstate commerce to be responsible for a violation of the Act. The fact that you caused the adulteration of an animal that was sold and subsequently offered for sale to a slaughterhouse that ships in interstate commerce is sufficient to make you responsible for violations of the Act. Similarly, it is not necessary for you to personally ship an adulterated drug in interstate commerce. The fact that you caused the adulteration of an animal drug that had been shipped in interstate commerce is sufficient to hold you responsible.

The above is not intended to be an all-inclusive list of violations. As a producer of animals that are offered for use as food, you are responsible for ensuring that your overall operations and the food you distribute are in compliance with the law, including the extralabel drug use regulations promulgated under the Act.

You should take prompt action to correct the above violations and to establish procedures whereby such violations do not recur. Failure to do so may result in regulatory action without further notice such as seizure and/or injunction.

You should notify this office in writing within 15 working days of receipt of this letter of the specific steps you have taken to correct the noted violations, including an explanation of each

step being taken to prevent the recurrence of similar violations. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed. Also include copies of any available documentation demonstrating that your corrections have been made.

Please send your written reply to the Food and Drug Administration, Attention: Lisa M. Elrand, Compliance Officer, 22201 23rd Drive SE, Bothell, WA 98021-4421. If you have any questions regarding this letter, please contact Ms. Elrand at (425) 483-4913

Sincerely,

Charles M. Breen
District Director

Enclosures: 21 CFR 556.510

cc: (w/copy of FDA-483):
Lael Alberg, DVM
U.S. Department of Agriculture
Food Safety & Inspection Service
Western Regional Office
620 Central Avenue, Building 2C
Alameda, California 94501